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James P. Naughton, Reg. No. 30, 665
Name of applicant, assignee or
Registered Representative

James P. Naughton
Signature

10/9/07
Date of Signature

PATENT
Client No.: 12730-231
(PA-5343-RFB)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 9896
David Ernest Hartley	Examiner: Prone, Christopher D.
Serial No.: 10/647,642	Group Art Unit No.: 3738
Filing Date: August 25, 2003	
For: ASYMMETRIC STENT GRAFT ATTACHMENT	

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

By the filing of this Appeal Brief in accordance with 37 CFR § 41.37, Appellant respectfully requests reconsideration by the Board of Patent Appeals and Interferences in the above-identified patent application. In particular, this is an appeal from the Pre-Appeal Brief Conference Decision dated May 7, 2007, Advisory Action mailed

October 26, 2006, and the Office Action dated September 13, 2006, wherein all of the pending claims were finally rejected.

I. REAL PARTY IN INTEREST

The real parties in interest are the assignees of the present application, namely William A. Cook Australia Pty. LTD., Cook Incorporated, and William Cook Europe.

II. RELATED APPEALS AND INTERFERENCES

The undersigned, Jeffery M. Duncan, is not aware of any other appeals, interferences, or other judicial proceedings that may be related to, would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22 are finally rejected under 35 U.S.C. § 103(a) for being obvious in view of U.S. Patent No. 5,873,906 to Lau et al. (*Lau et al.*) and U.S. Patent No. 5,562,726 to Chuter (*Chuter*).

Claims 2, 5, 6, 10, 13, 14, 20, 21, and 23 have been cancelled.

The above-mentioned rejection of claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22 is the subject of this Appeal.

IV. STATUS OF AMENDMENTS

On October 9, 2006, Applicant submitted an Amendment Made After Final in response to the Final Rejection of September 13, 2006. However, Applicant submitted only arguments and no amendments to the claims were made.

The Advisory Action of October 26, 2006 indicated that the Amendment Made After Final of October 9, 2006 was considered but failed to place the application in condition for allowance.

A Pre-Appeal Brief Request for Review was filed on March 13, 2007.

The Notice of Panel Decision for Pre-Appeal Brief Review of May 7, 2007 affirmed the rejection claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22.

V. SUMMARY OF CLAIMED SUBJECT MATTER

An understanding of the invention of independent claims 1, 9, and 22 can be gained upon review of the embodiments of the invention, described below, and illustrated in the figures of the specification. The application discloses an arrangement for mounting a stent graft prosthesis onto a deployment device. As used by the Appellant, the term "proximal" means closest to the heart or, in other words, furthest away from the doctor using the device. (Specification, page 2, lines 1-3). The term "distal" means furthest away from the heart, or closest to the doctor. (Specification, page 1, lines 15-18).

As defined by independent claims 1, 9, and 22, the stent graft prosthesis has a generally circular body end 1, as shown in FIG. 1, below. A deployment device for such a stent graft prosthesis has a retention arrangement 3 for the retention of the proximal end of the stent graft body end 1 to the deployment device, the mechanism for which is illustrated in FIG. 3. (Specification, page 11, lines 16-20). The retention arrangement 3 engages various points around the circumference of the stent graft body end 1 to the deployment device to give the asymmetric arrangement of folds as shown in FIG. 2. (Specification, page 11, lines 7-15).

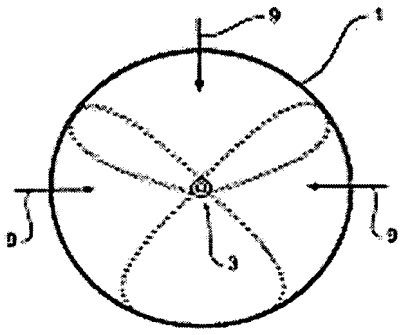


Fig 1

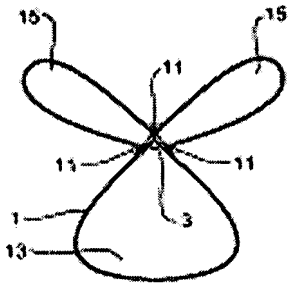


Fig 2

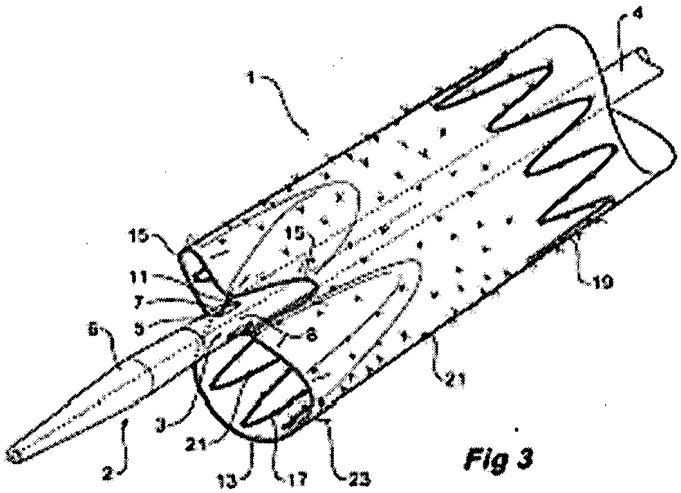


Fig 3

To provide for the retention of the stent graft, points of the circumference of the graft 1, as shown by the arrows 9 in FIG. 1, are drawn towards the retention arrangement 3 and retained by thread-like material 11 so that the end on view of the stent graft becomes substantially as shown in FIG. 2. (Specification, page 11, lines 16-20). This asymmetric arrangement of the stent graft attachment produces a larger fold 13 and two smaller folds 15, where the larger circumferential portion of the proximal end of the graft produces the larger fold 13 and the smaller circumferential portions of the proximal end of the graft produce the smaller folds 15. (Specification, page 11, lines 16-26).

The deployment device 2 has a guide wire catheter 4 and a trigger wire catheter 8 coaxially around the guide wire catheter 4, as illustrated in Figures 4 and 5, below. (Specification, page 12, lines 1-5). Trigger wires 5 pass along the annular space 10 between the guide wire catheter 4 and the trigger wire catheter 8 and exit through apertures 7 at the retention points at the proximal end of the prosthesis and then re-enter the annular space 10 between the guide wire catheter 4 and the trigger wire catheter 8 and pass into the nose cone 6, as shown in FIGS. 4 and 5. (Specification, page 12, lines 4-12).

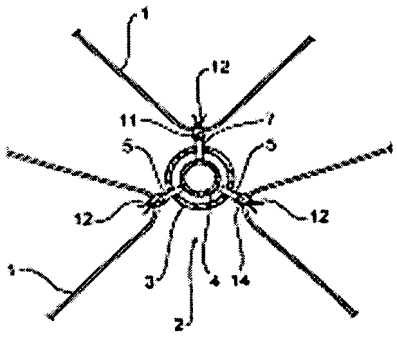


Fig 4

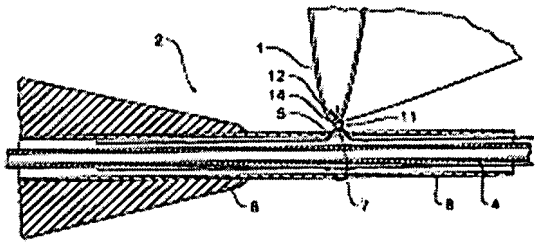


Fig 5

In one embodiment, the proximal end 38 of the graft is retained to the deployment device 32 by means of the stent graft retention of the present invention. As can be particularly seen in FIG. 7 below, the larger fold 13 of the stent graft is extended towards the inner side of the curve 31 of the thoracic arch 30. (Specification, page 13, lines 15-17). In this position, blood flow can flow through the larger fold 13 and cause it to extend against the inner wall 31 before the remainder of the stent graft fully engages the outer side of the curve 33. (Specification, page 13, lines 9-20). The larger fold allows for the placement of the prosthesis without the blood flow causing a portion of the graft to fold inward. (Specification, page 13, lines 24-29). Once blood flow is established through the larger fold 13, the remainder of the folds are released, as shown in FIG. 8. (*Id.*)

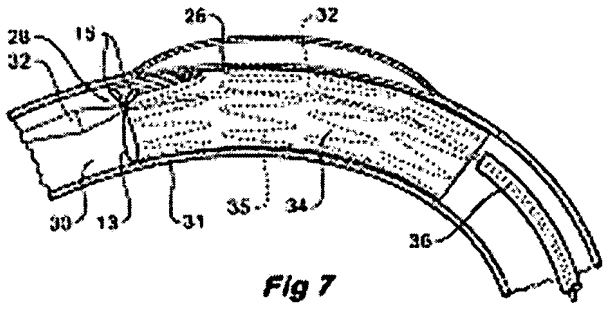


Fig 7

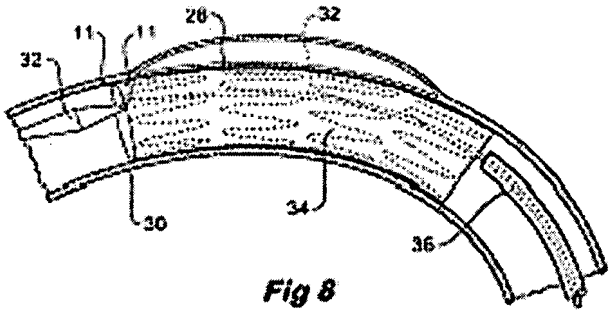


Fig 8

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,873,906 to Lau et al. ("*Lau et al.*") in view of U.S. Patent No. 5,562,726 to Chuter ("*Chuter*").

VII. ARGUMENT

A. Claims 1, 3, 4, 7-9, 11, 12, 15-19, and 22 are patentable over U.S. Patent No. 5,873,906 ("*Lau et al.*") in view of U.S. Patent No. 5,562,726 ("*Chuter*").

For the following reasons, Examiner Prone's rejection of all the pending claims under 35 U.S.C. § 103(a) as being obvious in view of *Lau et al.* and *Chuter* was improper.

Section 2142 of The Manual of Patent Examing Procedure (hereinafter MPEP) states that "[to] establish a prima facie case of obviousness . . . the prior art reference . . . must each or suggest **all** the claim limitations." MPEP § 2142 (emphasis added) (citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991)). However, the combination of *Lau et al.* and *Chuter* fails to teach, either expressly or inherently, several of the elements recited in the rejected claims. Although the absence of these elements has been brought to Examiner Prone's attention before, it appears that he has either misunderstood the teachings of the references, Appellant's claims, or both.

The patent to *Lau et al.* discloses a foldable stent that may be delivered to a body cavity or lumen and then expanded. *Lau et al.* teaches a foldable stent by providing loops or stitches connected by a tether wire 320, 322 which extends between

circumferentially spaced loops 324 and 326 along a portion of the body of the stent graft, as illustrated in Figures 21 and 22 below.

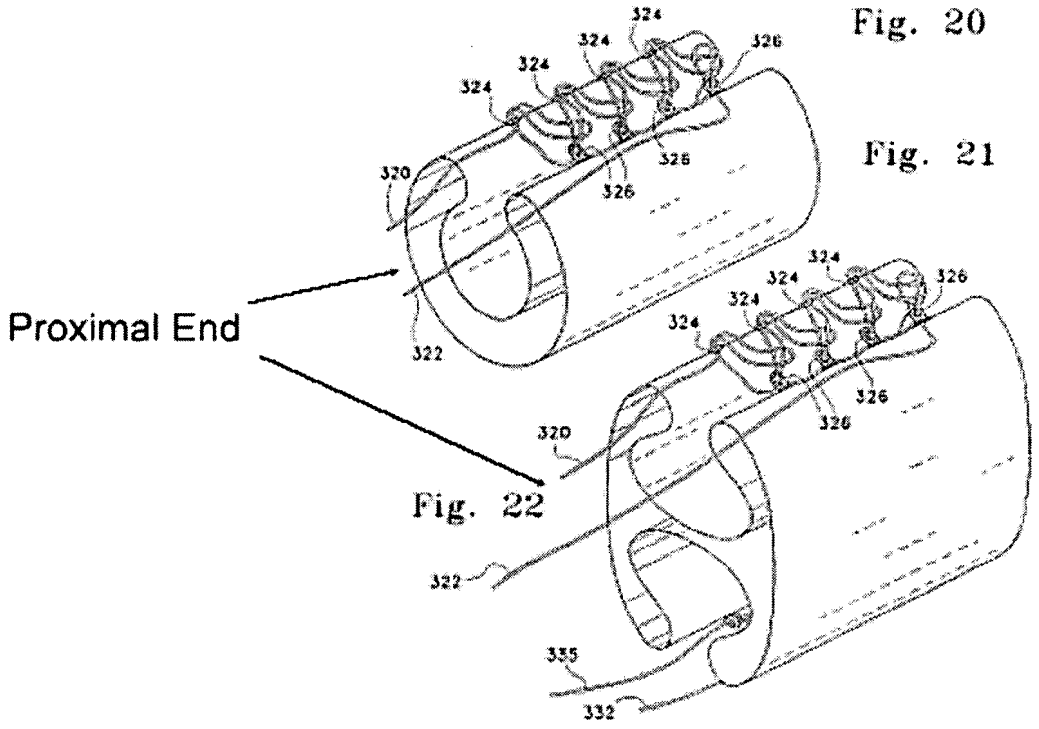


Fig. 20

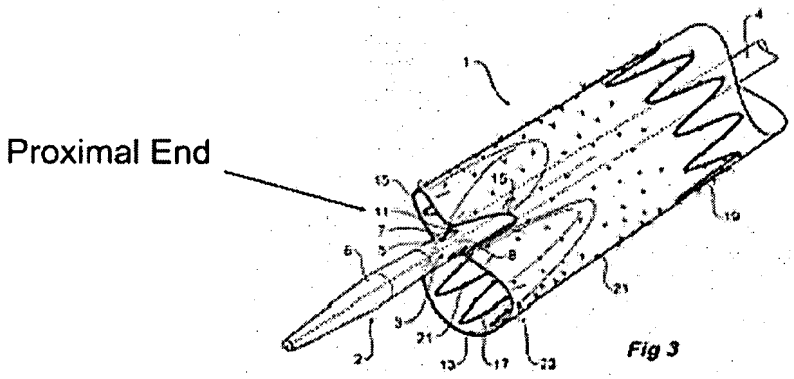
Fig. 21

Fig. 22

However, *Lau et al.*, does not disclose or teach the claimed trigger wire system. As discussed above, the claimed guide wire catheter has "a trigger wire catheter coaxially around the guide wire catheter with trigger wires passing along an annular space between the guide wire catheter and the trigger wire catheter . . . where the trigger wires are engaged with the graft material." In contrast, *Lau et al.* discloses a tether wire that laces around the outside of the prosthesis, and is not connected to a trigger wire catheter. The circumferentially spaced points along the length of the prosthesis in *Lau et al.* are connected to each other and not to a delivery device. The tether wire releases the prosthesis when it is pulled from the loops, and causes the circumference along the length of the prosthesis to expand.

Second, if, for the sake of argument, one were to consider *Lau et al.* as disclosing a trigger wire system, *Lau et al.*, does not show the retention of the proximal end of the prosthesis by the deployment device. As can be seen in Figures 21 and 22, the tether wire stops short of the end. As discussed previously, the present invention includes "a retention of the stent graft prosthesis to the guide wire catheter at a plurality

of retention points of the circumference of the proximal end of the stent graft prosthesis," as shown in FIG. 3, below.



Figures 21 and 22 of *Lau et al.* depict the use of multiple stent folds, each having a fixed end and a release end on their respective slip lines to fold the stent along its longitudinal axis. This configuration is in stark contrast with the claimed retention device where the proximal end of the prosthesis is secured during deployment. Contrary to Examiner Prone's belief, and as can be seen in Figures 21 and 22, the loops 324 and 326 are spaced along a portion of the longitudinal axis of the body, excluding the proximal end of the stent. Such a configuration will not prevent the folding of the proximal end prosthesis under the influence of pulsating blood flow, and in fact will increase the likelihood of occluding the lumen, a catastrophic event the present invention seeks to prevent.

Third, the configuration of the tether wire of *Lau et al.* does not produce the "a greater circumferential distance between two adjacent retention points than other of the points" as claimed in the present invention and discussed in more detail, above. In fact, such a lobe configuration is a feature that the *Lau et al.* reference sought to prevent. The specification of *Lau et al.* teaches that to prevent the untwisting of the torsion members when folded down to a reduced diameter, "[t]he stent-graft is folded along its longitudinal axis and restrained from springing open." (*Lau et al.*, Col. 16, ll. 25-37). In light of this statement, Appellant submits that *Lau et al.* clearly could not have, and in fact does not have, a stent having uneven sized lobes or a stent not folded along its longitudinal axis. An asymmetrical lobe arrangement would not prevent the untwisting of the torsion members, thus defeating one purpose of the restraining mechanism

disclosed in *Lau et al.* (*Lau et al.*, Col 16, ll. 25-35). Accordingly, *Lau et al.*, teaches away from a stent having such a configuration. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be lead in a direction divergent from the path that was taken by the applicant. *See Tech Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999).

For at least these reasons, *Lau et al.* falls woefully short in teaching or suggesting the claimed device.

Examiner Prone has combined the teachings of *Lau et al.* with *Chuter*. However, he has not articulated any reason why this combination would have been obvious. *In re Khan*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). Neither reference creates an inference or a creative step that a person of ordinary skill in the art would employ to combine these references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, Lexis 4745, at *32 (Apr. 30, 2007); *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007).

Moreover, even if properly combined, *Chuter* does not make up the deficiencies in *Lau et al.* *Chuter* does not teach the differences in the circumferential distances at the proximal end of the prosthesis that would produce uneven lobes, and prevent a portion of the prosthesis to fold over during insertion.

Because the combination, assuming *arguendo* it is proper, of *Lau et al.* and *Chuter* does not teach all of the claim limitations of independent claims 1, 9, and 22, it logically follows that dependent claims 3, 4, 7, 8, 11, 12, and 15-19, are also in condition for allowance. Indeed, because each of these dependent claims have additional limitations, they are further patentable over the cited references. For example, and without limitation, dependent claim 3 further requires that the retention arrangement include "three retention points so that one larger and two smaller folds of the graft material are formed." Clearly, if the proposed combination of *Lau et al.* and *Chuter* does not disclose "a greater circumferential distance between two adjacent retention points than other of the points" as required by claim 1, it surely cannot, and in fact does not,

disclose "three retention points so that one larger and two smaller folds of the graft material are formed."

In view of these important distinctions, the combination of *Lau et al.* and *Chuter* would not have made Appellant's invention obvious.

VIII. CONCLUSION

The cited references in combination with the Examiner's assertions do not establish a *prima facie* case of obviousness. Accordingly, the rejection should be reversed.

Respectfully submitted,

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Dated: October 9, 2007

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CLAIMS APPENDIX

CLAIMS ON APPEAL

1. A stent graft prosthesis mounted to a deployment device and adapted to be deployed in a curved lumen, the curved lumen having an inner side and an outer side of the curve, the stent graft prosthesis being temporarily mounted to the deployment device at at least one end of the prosthesis by a retention arrangement, the retention arrangement including a retention of the stent graft prosthesis to the guide wire_catheter at a plurality of retention points of the circumference of the proximal end of the stent graft prosthesis, there being a greater circumferential distance between two adjacent retention points than other of the points, wherein the guide wire catheter includes a trigger wire catheter coaxially around the guide wire catheter with trigger wires passing along an annular space between the guide wire catheter and the trigger wire catheter and exiting through apertures in the trigger wire catheter at the retention points and the trigger wires are engaged with the graft material to provide the retention points and the apertures are equally spaced around the trigger wire catheter whereby when the deployment device is deployed in the curved lumen the greater circumferential distance is on the inner side of the curve.

2. (Cancelled)

3. A stent graft prosthesis mounted to a deployment device as in claim 1 wherein the retention arrangement includes three retention points so that one larger and two smaller folds of the graft material are formed.

4. A stent graft prosthesis mounted to a deployment device as in claim 1 wherein the retention arrangement provides one larger lobe and at least one smaller lobe of the proximal end of the graft material wherein the larger lobe is on the inner side of the curve when the deployment device is deployed in the curved lumen.

5. (Cancelled)

6. (Cancelled)

7. A stent graft prosthesis mounted to a deployment device as in Claim 1 wherein the trigger wires are engaged to the graft material by loops of thread-like material.

8. A stent graft prosthesis mounted to a deployment device as in claim 7 wherein the loops of thread-like material are adapted to remain with the graft material after deployment.

9. A deployment device and stent graft prosthesis temporarily mounted thereto and adapted to be deployed in a curved lumen, the curved lumen having an inner side and an outer side of the curve, the deployment device including a deployment catheter and a release mechanism, the stent graft prosthesis comprising a tube of graft material having a first end and a second end and being mounted to the deployment device at at least its first end by a retention arrangement, the retention arrangement including a retention to the deployment device at a plurality of points of the circumference of the proximal end of the stent graft prosthesis, there being a greater circumferential distance between two adjacent retention points than other of the points, wherein the deployment catheter includes a guide wire catheter and a trigger wire catheter coaxially around the guide wire catheter and the release mechanism includes trigger wires passing along the annular space between the guide wire catheter and the trigger wire catheter and exiting through apertures in the trigger wire catheter and the apertures are equally spaced around the trigger wire catheter, whereby when the deployment device is deployed in the curved lumen the greater circumferential distance is on the inner side of the curve.

10. (Cancelled)

11. A deployment device and stent graft prosthesis temporarily mounted thereto wherein the retention arrangement includes three retention points so that one larger and

two smaller folds of the graft material are formed.

12. A deployment device and stent graft prosthesis temporarily mounted thereto as in Claim 9 wherein the retention arrangement provides one larger fold and at least one smaller fold of the proximal end of the graft material wherein the larger fold is on the inner side of the curve when the deployment device is deployed in the curved lumen.

13. (Cancelled)

14. (Cancelled)

15. A deployment device and stent graft prosthesis temporarily mounted thereto as in Claim 9 wherein the trigger wires are engaged to the graft material by loops of thread-like material.

16. A deployment device and stent graft prosthesis temporarily mounted thereto as in Claim 15 wherein the loops of thread-like material are adapted to remain within the graft material after deployment.

17. A deployment device and stent graft prosthesis temporarily mounted thereto as in Claim 9 wherein the stent graft prosthesis comprises of self expanding zig zag Z stents.

18. A deployment device and stent graft prosthesis temporarily mounted thereto as in Claim 17 wherein the retention is by sutures tied to trigger wires on the deployment device and around bends of the zig zag Z stents on the stent graft.

19. A deployment device and stent graft prosthesis temporarily mounted thereto as in Claim 9 wherein further retention points are provided along the length of the stent graft prosthesis.

20. (Cancelled)

21. (Cancelled)

22. A deployment device for deploying a stent graft prosthesis into a thoracic arch of a patient, the stent graft prosthesis being temporarily mounted to the deployment device and adapted to be deployed in the thoracic arch, the thoracic arch having a curved lumen having an inner side and an outer side of the curve, the stent graft prosthesis being mounted to the deployment device at least the proximal end of the prosthesis by a retention arrangement, the retention arrangement including a retention to the deployment device at a plurality of points of the circumference of the proximal end of the stent graft prosthesis, there being a greater circumferential distance between two adjacent retention points than other of the points, wherein the deployment device includes a guide wire catheter and a trigger wire catheter coaxially around the guide wire catheter and the retention arrangement includes trigger wires passing along the annular space between the guide wire catheter and the trigger wire catheter and exiting through apertures in the trigger wire catheter and the apertures are equally spaced around the trigger wire catheter, whereby when the deployment device is deployed in the curved lumen the greater circumferential distance is on the inner side of the curve.

23. (Cancelled)

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None